UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

NOV 3 0 2015

REPLY TO THE ATTENTION OF:

E-19J

Michelle Moser
Division of License Renewal
Nuclear Regulatory Commission
Office of Nuclear Reactor Regulation
Mail Stop O-11F1
11555 Rockville Pike
Rockville, Maryland 20852

Re: **Final Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility, Janesville, Wisconsin – NUREG-2183 – CEQ #20150299**

Dear Ms. Moser:

The U.S. Environmental Protection Agency has reviewed the Final Environmental Impact Statement (EIS) for the SHINE Medical Radioisotope Production Facility in Janesville, Wisconsin, as prepared by the Nuclear Regulatory Commission (NRC). Our comments are provided pursuant to the National Environmental Policy Act (NEPA), the Council on Environmental Quality's NEPA Implementing Regulations found at 40 CFR 1500-1508, and Section 309 of the Clean Air Act.

SHINE Medical Technologies, Inc. (the Applicant) applied to the NRC for a construction permit to build and operate a medical radioisotope production facility in Janesville, Wisconsin. The U.S. Department of Energy (DOE) is a cooperating agency and must decide whether to provide cost-sharing financial support to the Applicant under a cooperative agreement, which will accelerate the commercial production of medical radioisotopes without the use of highly enriched uranium. The proposed preferred alternative is for NRC to issue the license.

EPA provided comments on the Draft EIS in a letter dated July 2, 2015, assigning a rating of Environmental Concerns – Adequate Information (EC-1). Our comments primarily focused on waste stream management, recommendations of additional mitigation measures, and parts of the Draft EIS that required clarity.

Based on our review of the Final EIS, we recommend no further information or clarifications on the following comments from the Draft EIS:

Recycled/Recyclable • Printed with Vegetable Oil Based Inks on 100% Recycled Paper (100% Post-Consumer)

- ***Radiation* (Draft EIS - Comment 6-2):** EPA previously recommended that the Final EIS clarify the UREX process, including raffinate generation, storage, and waste streams. EPA has re-reviewed sections of the Environmental Report (ER), particularly Table 19.2.5-1 and Section 19.2.5.3.2. The term "low specific activity" is a U.S. Department of Transportation (DOT) designation for shipment of radioactive materials, not a waste disposal designation as stated in NRC's response. Section 19.2.5.3.2 of the ER (*Liquid Radioactive Waste System*) provides a more accurate description of the management of the liquid radioactive wastes.

  Further, EPA appreciates the additional information provided in the October 1, 2015 letter from SHINE to NRC (*SHINE Medical Technologies, Inc. Application for Construction Permit Description of the SHINE Process for Preparing Consolidated Liquid Waste Streams for Disposal as Class A Waste*), which provides sufficient clarification on the processing and management of the UREX raffinate waste stream.

  EPA does not require further information or clarification on this comment.

- ***Radiation* (Draft EIS – Comments 6-3, 6-4, 6-5, 6-6, and 6-7[1]):** These comments recommended clarification or additional information on the radioactive materials generation, storage, and waste stream processes. NRC provided sufficient information in the Final EIS; no further clarification is required.
- ***Green Infrastructure* (Draft EIS – Comment 6-8):** EPA recommended green infrastructure mitigation measures. NRC forwarded these recommendations to the applicant and included the measures (as recommendations) in Section 6.3.1 of the Final EIS. No further clarification or information is needed.
- ***Climate Change and Greenhouse Gases* (Draft EIS – Comment 6-9):** EPA recommended the Final EIS include measures to reduce greenhouse gas emissions and improve climate resiliency. NRC clarified that SHINE committed to the following in the ER: participating in several climate and green power initiatives; developing a greenhouse gas inventory program; implementing energy efficiency and conservation programs; and, encouraging carpooling and other programs to reduce vehicle traffic during construction and operation. These measures were included in Table 6-2 of the Final EIS. EPA commends the applicant for committing to these measures. No further clarification or information is needed.
- ***Transportation* (Draft EIS – Comment 6-10):** This comment recommended on-going coordination during construction and operation between the applicant and the Wisconsin Department of Transportation and the Janesville Transit System in order to maintain appropriate levels of service. NRC forwarded these recommendations to the applicant and recommended mitigation has been added to Section 6.3.1. No further information or clarification is needed.

[1] NRC assigned numbers to comments in the Final EIS.

- ***Editorial* (Draft EIS – Comments 6-11, 6-12, and 6-13):** These comments were editorial in nature; no further information or clarification is needed.

EPA retains the following comment and recommendation, based on information provided in the Final EIS and ER, in addition to follow-up conversations held between NRC and EPA:

- ***Radiation* (Draft EIS - Comment 6-1):** NRC states in Table 19.2.5-1 of the ER "*that waste streams would be stored on site, during which time decay would occur such that the material would be sent to Waste Control Specialists (WCS) for disposal as Class B waste. Therefore, no GTCC* [Greater Than Class C (wastes)] *would be transported off the SHINE site.*" The table does not provide information on waste storage location, although it is mentioned elsewhere in this chapter. Column 3 of Table 19.2.5-1 provides information on the waste classification *as generated.* Column 8 of Table 19.2.5-1 provides info on the U.S. DOT shipment type for the waste streams. For example, given the information provided in the Table, the zeolite beds are generated as GTCC, and shipped in a Type B container to WCS. However, it cannot be inferred from Table 19.2.5-1 that *"no GTCC would be transported off the SHINE site."*

  As detailed in Chapter 19.2.5.3.1 of the ER (*Solid Radioactive Waste Handling System*) states the following with regard to the zeolite bed solids:

  > *Only iodine is adsorbed in the zeolite beds. The waste classification for this material is a function of both the efficiency of the zeolite beds and the change out frequency of the beds. It is likely the beds, in terms of operational lifetime, could build up enough iodine-129 to be greater than Class C (GTCC) waste. The zeolite is shipped to an off-site processor. The shipment is a Type B shipment and occurs infrequently.*

  Iodine-129 has a half-life of 15.7 million years; if Iodine-129 activity is driving the GTCC designation then decay-in-storage does not seem practical. Chapter 19.2.5.3.1 also states that the zeolite material may exceed toxicity characteristic leaching procedure (TCLP) regulatory levels, and if so then the zeolite waste stream would be a mixed low level waste (MLLW). Mixed waste is jointly regulated under both the Resource Conservation and Recovery Act (RCRA) and the Atomic Energy Act (AEA). RCRA applies to the hazardous waste portion of the waste as any other hazardous waste, while AEA applies to the RCRA-exempt radioactive portion (52 FR 15939; May 1, 1987). While solidification and processing of zeolite at Waste Control Specialists (WCS) is mentioned in Chapter 19.2.5.3.1, the resulting waste classification following solidification/processing is not clear.

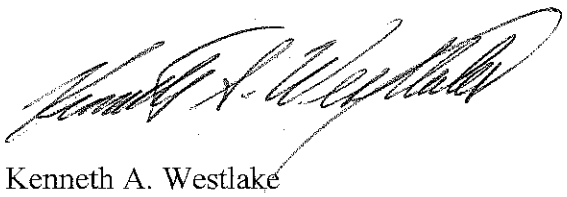
  It should also be noted that Chapter 19.2.5.3.1 discusses the ion exchange resin and associated cesium-137 (30 year half-life), and Table 19.2.5-1 states that the Cs/Ce Media Resin is generated as GTCC as well. Chapter 19.2.5.3.1 also states "*the spent resins are solidified in a shielded waste processing hot cell* and *the used resin is classified as GTCC*

waste and is shipped as Type B to an off-site location for long-term storage at WCS." We note that Section 2.7.1.2 of the EIS (*Liquid and Solid Waste*) states "*if a disposal pathway for GTCC waste does not exist, DOE will be responsible for its safe storage and disposal.*"

> **Recommendation:** NRC and SHINE should ensure the minimization of GTCC generation and should avoid generating waste without a clear treatment and disposal path.

Thank you in advance for your consideration of our recommendations to reduce environmental impacts of the project and to improve the quality of the document. Please be aware that we reserve the right to provide additional comments or recommendations under other permitting processes. If you have any questions, please feel free to contact Elizabeth Poole of my staff at 312-353-2087 or poole.elizabeth@epa.gov.

Sincerely,



Kenneth A. Westlake
Chief, NEPA Implementation Section
Office of Enforcement and Compliance Assurance

Cc (via email): Randy Howell, Department of Energy
Jim Costedio, SHINE Medical Technologies, Inc.
Mark Freitag, City of Janesville
Bethaney Bacher-Gresock, Federal Highway Administration - Wisconsin
Ian Chidester, Federal Highway Administration - Wisconsin
Jay Waldschmidt, Wisconsin Department of Transportation
Roseanne Meer, Wisconsin Department of Transportation - Southwest
Rebecca Smith, Janesville Transit System
Alice Halpin, Department of Agriculture, Trade, and Consumer Protection